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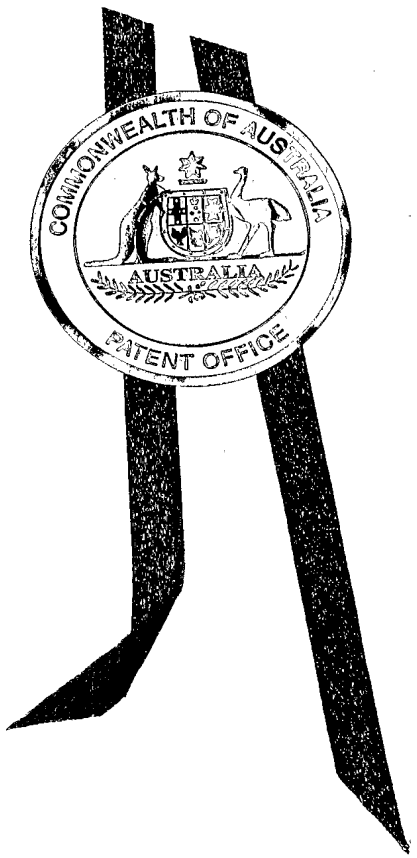

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Sixteenth day of February 2005

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Improvements to a Blood Collection Device

Field of the Invention.

This invention is directed to a blood collecting device which has a needle, a housing, which uses a vacuum tube to collect the blood, and where the needle can be retracted after use in such a manner that needlestick injury is reduced or eliminated. The invention will be described with reference to its use to collect blood, but it should be appreciated that the device may also be used to collect other types of body fluids.

Background Art.

It is very well-known and standard practice to collect blood from a patient using a device commonly known as a "vacutainer". This type of known device has a double ended needle which is fitted to a housing. The housing approximates a shortened syringe barrel. The double ended needle is fitted to the housing such that a longer part of the needle extends from the housing and a shorter part of the needle extends into the housing. To take blood from a patient, the longer part of the needle is inserted into a blood vessel. The blood is collected into a container which approximates a test tube and which can be made of glass or plastic. The container has an open end which is covered by a rubber stopper (or stopper made of other material), and the container is partially evacuated. The container is pushed up into the housing until such time as the inner end of the needle pieces the rubber stopper. The partial vacuum in the container causes blood to be sucked through the needle and into the container. When the blood collection is completed, the container is removed from the housing. The housing containing the attached needle is then pulled back to remove the needle from the blood vessel. The housing containing the attached needle then needs to be disposed of in a safe manner but it is at this point that needlestick injury can occur as the needle is (a) contaminated and the needle (b) projects from the front of the housing.

Therefore, there would be an advantage if it were possible to have a blood collecting device which still uses the above principle of a partially evacuated container, but which has some form of mechanism to enable the needle to be retracted to reduce or even to the eliminate the possibility of needlestick injury.

It will be clearly understood that, if a prior art publication is referred to herein, this reference does not constitute an admission that the publication forms part of the common general knowledge in the art in Australia or in any other country.

Object of the Invention.

It is an object of the invention to provide a blood collection device that may overcome or reduce the possibility of needlestick injury.

In one form, the invention resides in a blood collection device comprising a housing, a needle holder, a needle which is double ended and has a first end (outer end) that projects from the housing and a second end (inner end) that projects into the housing, the needle holder being releasably attached relative to the housing to enable the needle holder and the attached needle to be retracted.

In another form, the invention resides in a blood collection device assembly comprising a blood collection device as described above, and a needle retraction device, the needle retraction device able to be pushed into the housing to release the needle holder from the housing and to retract the needle holder containing the attached needle into the needle retraction device.

In this manner, blood can be collected in a manner not dissimilar to the "vacutainer" technique. However, once the required volume of blood has been collected, instead of simply pulling the needle out of the blood vessel and having a contaminated projecting needle which creates a sharps risk, a needle retraction device is pushed into the housing and towards the end of the housing which functions to decouple the needle holder (containing the contaminated needle) from the housing and then retracts the needle into the needle retraction device which functions to protect the needle against needlestick injury. It is considered that this technique will be much safer and very easy to use, and there is very little likelihood that the contaminated needle can be touched.

The blood collection device comprises the housing, a needle holder and a needle which is generally well-known. However, as part of the present invention, the needle holder is releasably attached relative to the housing to enable the needle holder to be retracted into a separate needle retraction device.

The housing will typically comprise an elongate cylindrical hollow body into which a blood collecting container can pass. The body will typically have an

open rear end to enable the blood collecting container to be pushed into the housing. The front of the housing will typically have a configuration to enable the needle holder to be attached to the front of the housing. Typically, the front of the housing will have a smaller diameter extending collar. The collar may be provided with engagement means to enable the needle holder to be releasably attached relative to the collar. The engagement means may comprise a recess. The recess may be an annular recess. It is envisaged that a plurality of recesses may be provided or that the recess is a single recess or a plurality of recesses. The recess may comprise a small groove extending along the inner wall of the collar. Alternatively, the engagement means may comprise a projection or a plurality of projections.

The needle holder will typically be provided with an internal passageway to accommodate the steel needle. Suitably, the needle holder is provided with engagement means to engage with the housing and particularly to engage with the collar. If the engagement means on the collar comprises a recess, the engagement means on the needle holder will typically comprise a projection that can engage with the recess to hold the needle holder to the collar and therefore to the housing. However, if the engagement means on the collar comprises a projection, the engagement means on the needle holder will typically comprise a recess. It is envisaged that the engagement means on the needle holder may comprise a plurality of projections, a plurality of recesses, or a combination thereof. Typically however, the engagement means on the needle holder will comprise a projection and will typically comprise a small annular rib that can engage into the small annular recess on the collar.

The needle holder may be formed from separate parts and will typically be formed from two parts being a larger internal part and a smaller external part. The internal part may be provided with the passageway to accommodate the steel needle and can be seen as the "main body" of the needle holder. The external part may extend about the main body or at least partially about the main body and will typically be provided with the engagement means. The external part and the internal part can be attached together by any suitable means.

The needle may be a conventional blood collecting needle which is well-known in the art.

The blood collecting containers that are used to collect blood may be of

conventional design and these will typically comprise an elongate hollow body which is partially evacuated and which is provided with a pierceable front stopper. As the container is pushed through the housing, the inner part of the needle will pierce the front stopper and the partial vacuum in the container will cause blood to be sucked through the needle and into the container. This arrangement is well-known.

The needle retraction device will typically be a separate part which is inserted into the housing only after sufficient blood has been collected in the blood collecting containers, and it is now desirable to retract the needle in a safe manner. The needle retraction device will typically comprise an elongate body that can be at least partially pushed into the housing. The elongate body may therefore be substantially tubular. The elongate body will typically have an evacuated chamber in the body, and the function of the chamber will be to accommodate the needle and the needle holder in a safe manner.

The evacuated chamber will typically have an open front end which is plugged with a plug. The plug will typically be slideable along the chamber and in a sealing manner and therefore the plug may be provided with sealing means to enable the plug to be sealed on the inside wall of the evacuated chamber but still able to slide along the evacuated chamber. The sealing means may comprise sealing rings. The plug may itself be provided with an internal chamber, and the internal chamber may function to accommodate the part of the needle that extends inside the housing. This internal chamber does not need to be evacuated. If desired, the front of the plug may have a pierceable or frangible wall.

The plug is releasably attached relative to the body of the needle retraction device to prevent the plug from being sucked back into the partially evacuated chamber. Typically, the plug will contain a releasable engagement means which may comprise a resilient member or portion which attaches to the body. However, upon movement of the engagement means to the free position, the plug will now be released from the body and will be sucked back into the partially evacuated chamber.

The construction and arrangement of the needle retraction device and particularly the front part of the needle retraction device is such that when the device is pushed into the housing and against the inner end of the housing, the plug and typically the engagement means on the plug will couple to the needle holder and this

coupling motion will also release the needle holder from the housing. As well, this coupling motion will also release the plug from the body of the needle retraction device. Thus, the plug will be sucked back into the evacuated chamber, and as the plug is attached to the needle holder, will also cause the needle holder to be sucked back into the chamber.

Suitably, a locking means is provided to lock the needle retraction device in the housing once the needle has been sucked into the needle retraction device. The locking means may function to prevent the needle retraction device from being withdrawn from the housing. The entire assembly can then be disposed of in a safe manner.

Brief Description of the Drawings.

An embodiment of the invention will be described with reference to the following drawings in which:

Figure 1. Illustrates a blood collection device according to an embodiment of the invention together with a conventional blood collecting chamber which is partially pushed into the housing.

Figure 2. Illustrates the device of Figure 1 but this time with the conventional blood collecting chamber being pushed fully into the housing to enable blood to be sucked into the chamber.

Figure 3. Illustrates a needle retraction device which is a separate member and which has been partially pushed into the housing.

Figure 4. Illustrates the device of figure 3 now having been pushed into the fully forward position to couple against the needle holder and to release the needle holder from attachment to the housing.

Figure 5. Illustrates the contaminated needle and needle holder, and the plug which forms part of the needle retraction device being sucked back into the needle retraction device to protect against needlestick injury.

Figure 6. Illustrates in greater detail the initial process of decoupling the needle holder from the housing and decoupling the plug from the needle retraction device.

Figure 7. Illustrates in greater detail the final process of decoupling the needle holder from the housing and decoupling the plug from the needle retraction device.

Figure 8. Illustrates a section view of the needle retraction device in the fully

forward position.

Figure 9. Illustrates an enlarged section view of figure 8.

Figure 10. Illustrates a locking device to lock the needle retraction device against the housing.

Best Mode.

Referring to the drawings and initially to figures one and two there is illustrated a blood collection device according to an embodiment of the invention. Basically, the blood collection device comprises three main portions being a housing 10, a needle holder 11 and a double ended needle 12. Also illustrated in the figures is a blood collection chamber 13 which is of conventional design and which comprises a partially evacuated chamber body which is sealed with a forward plug 14 which can be pierced by the inner part of needle 12.

Housing 10 is tubular in configuration and will typically be made of plastics material and has a rear portion provided with an outwardly extending flange 15, the flange functioning to assist with a one-handed operation of the needle retraction device that will be described in greater detail below. Flange 15 however is quite similar to the flanges on syringes. Housing 10 is entirely hollow to enable chamber 13 to pass into the housing and towards the inner end of needle 12.

The front part of housing 10 is provided with an extending collar 16 which is described in greater detail in figure six and figure seven. Collar 16 has a first annular portion 17 which extends substantially at right angles from the front of housing 10. The first annular portion extends into a second annular portion 18 which tapers and which extends into a small third annular portion 19 which is again at right angles relative to the front of housing 10. The first annular portion 17 is provided with a small internal annular groove 20 which forms part of the engagement means to engage the needle holder 11 to collar 16.

Needle holder 11 in the particular embodiment is formed in two parts being a larger internal part 21 and a smaller external part 22. The internal part 21 contains a passageway to accommodate the steel needle 12. The external part 22 extends about the inner portion of internal part 21 and accommodates the engagement means that releasably attaches the entire needle assembly relative to collar 16. Specifically, external part 22 is provided with an annular flange 23 which is best

illustrated in figure seven. Flange 23 extends against the inside wall of first portion 17 and part of second portion 18. Flange 23 is manufactured to have a bias to press against the inside wall of collar 16. The portion of flange 23 that presses against the inside wall of first portion 17 is provided with a small extending rib 24 that engages into the groove 20 which is on first portion 17. Thus, this arrangement holds the needle holder against collar 16. Flange 23 however also terminates into a small angled lip 25 which projects slightly away from the junction of collar 16 and the remainder of housing 10 to provide a very small but significant gap, and this arrangement is to facilitate decoupling of the needle holder from the housing by the needle retraction device and this will be described in greater detail below.

Thus, as long as flange 23 is not interfered with or manipulated, it causes the needle holder 11 remain attached to collar 16.

With this arrangement, a blood collection chamber 13 (see figure one) can be pushed into housing and against the inner part of needle 12 and upon further pushing (see figure two) the inner part of the needle pierces the plug 14 of chamber 13 to expose the needle to the partial vacuum inside the chamber. The partial vacuum causes blood to be sucked through the needle and into the chamber. Once the chamber is sealed or has a desired quantity of blood, it can be simply pulled out of housing 10. Sometimes, a plurality of such chambers is used to provide a greater volume of blood.

Once all the blood has been collected, the next step of the present invention is to enable the needle to be retracted to prevent needlestick injury. This requires a separate device being the needle retraction device 28 and this device is illustrated in figures three-five. Basically, the needle retraction device 28 comprises an elongate body 29 which has a partially evacuated chamber 30. The rear part of device 28 is provided with a thumb or palm depressible portion 31 to facilitate pushing of the device into housing 10. The front of chamber 30 is open but is sealed with a plug 32. Plug 32 is designed to enable it to be sucked back into chamber 30 but in a sealing manner and therefore the outer wall of plug 32 contains annular sealing ribs 33 (see figure 7). This is not dissimilar to the plunger of a syringe. Plug 32 is however prevented from being sucked back into the partially evacuated chamber 30 by being releasably locked onto body 29. Specifically, and best illustrated in figure six, plug 32 is provided with an annular flange 34 which is resilient but which is naturally biased against the inside wall of body 29. The outermost edge of annular flange 34 is

provided with an abutment 35 which is generally "arrow" shaped, and has a face which abuts against the front edge of body 29 and therefore locks the plug against body 29 against being sucked back into the evacuated chamber 30. Therefore, as long as abutment 35 engages with the front edge of body 29, the plug can not be sucked back into the chamber.

Plug 32 is provided with its own internal chamber 36 the function of which is to accommodate the inner part of needle 12, this being best illustrated in figure three. A small sealing membrane 37 is provided over the front of plug 32 and which can be pierced by the inner end of needle 12. The internal chamber 36 of plug 32 is not evacuated and the sealing membrane 37 is there to provide a clean finish and to prevent debris from passing into the chamber.

When the needle retraction device 28 is inserted into housing 10 and pushed all away to the end of housing 10, the contaminated needle and needle holder are sucked back into chamber 30 as follows: firstly, and particularly referring to figure six and figure seven, as the front of body 29 comes up against the inner end of housing 10, the abutment 35 on the edge of annular flange 34 begins to contact the inner edge between first portion 17 and the remainder of housing 10, and this inner edge 40 is ramped (this being best illustrated in figure six and figure seven). Moreover, the shape of abutment 35 is such that further forward movement of body 29 causes the abutment to ride along the ramped inner edge 40 and to be pressed inwardly. As the abutment is pressed inwardly, it becomes released from engagement with body 29 and therefore plug 32 becomes released from body 29. At the same time, the inward movement of abutment 35 causes the abutment to engage with the small lip 25 which is on the free end of annular flange 23 which forms part of the needle holder 11. Moreover, as well as engaging with the small lip 25, the inward movement also causes the annular flange 23 to move inwardly and this releases the small rib 24 from engagement with groove 20. Thus, the needle holder has now been decoupled or released from engagement with the housing, as well as the plug 32 becoming released or decoupled from body 29. The vacuum inside chamber 30 now causes plug 32 to be sucked back into the chamber, and as the plug is now coupled to the needle holder, the needle holder is also sucked back into the chamber. This final position is illustrated in figure five. When the needle holder (containing the contaminated needle) is sucked back into the chamber, and as illustrated in figure five, the needle is completely

shielded by body 29.

However, to provide even further security, it is preferred that the needle retraction device 28 is locked against housing 10 once it has achieved a position of figure four or figure five and thus the needle retraction device 28 cannot be removed. This can be achieved by a small locking arrangement 42 which is best illustrated in figure 10. The locking arrangement comprises a small outwardly biased rib 43 which forms part of body 29 and which engages in a small slot 44 which forms part of housing 10. Thus, as the needle retraction device 28 is pushed fully into housing 10 (see figure four and figure five), rib 43 springs outwardly into engagement with slot 44 and the needle retraction device cannot be retracted back out of housing 10.

Throughout the specification and the claims (if present), unless the context requires otherwise, the term "comprise", or variations such as "comprises" or "comprising", will be understood to apply the inclusion of the stated integer or group of integers but not the exclusion of any other integer or group of integers.

Throughout the specification and claims (if present), unless the context requires otherwise, the term "substantially" or "about" will be understood to not be limited to the value for the range qualified by the terms.

It should be appreciated that various other changes and modifications can be made to any embodiment described without departing from the spirit and scope of the invention.

Dated this 23rd day of January 2004

Medigard Limited

By its Patent Attorneys

Cullen & Co.

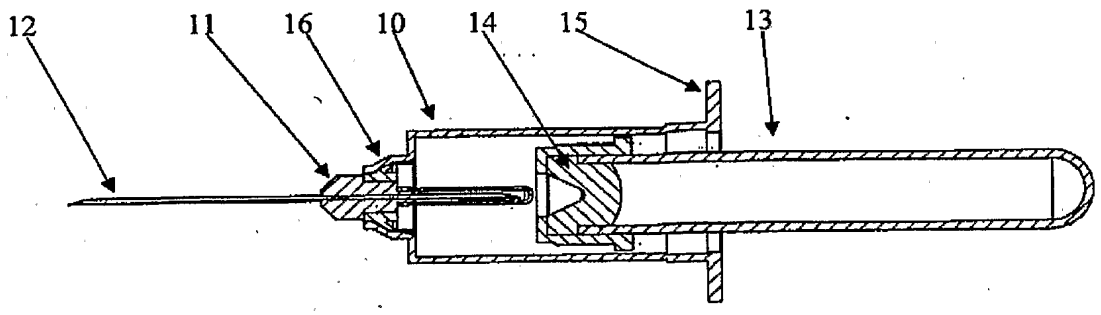

FIG 1

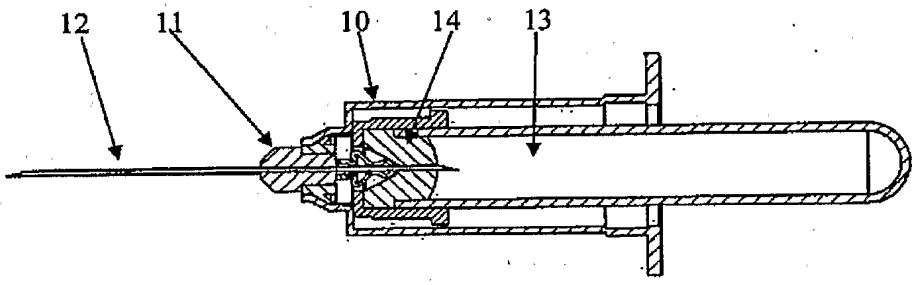

FIG 2

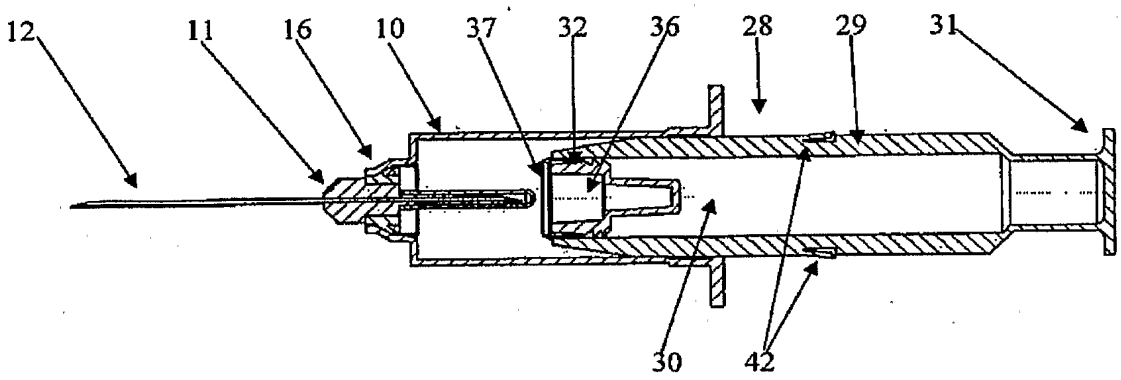

FIG 3

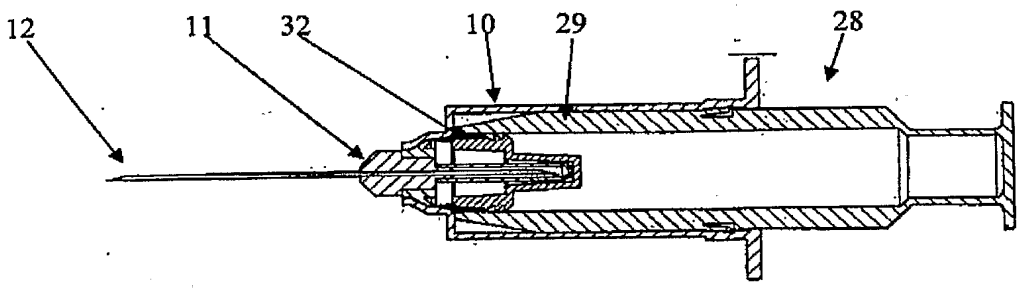

FIG 4

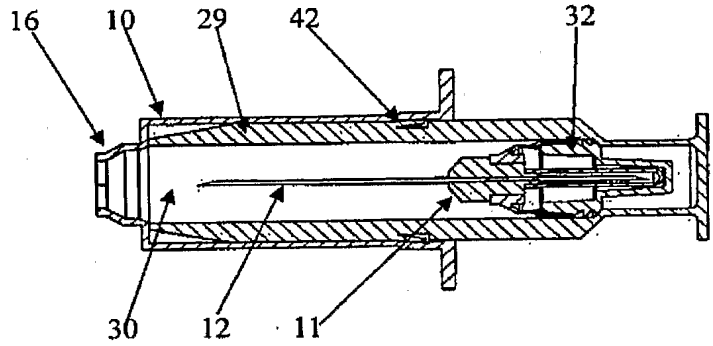

FIG 5

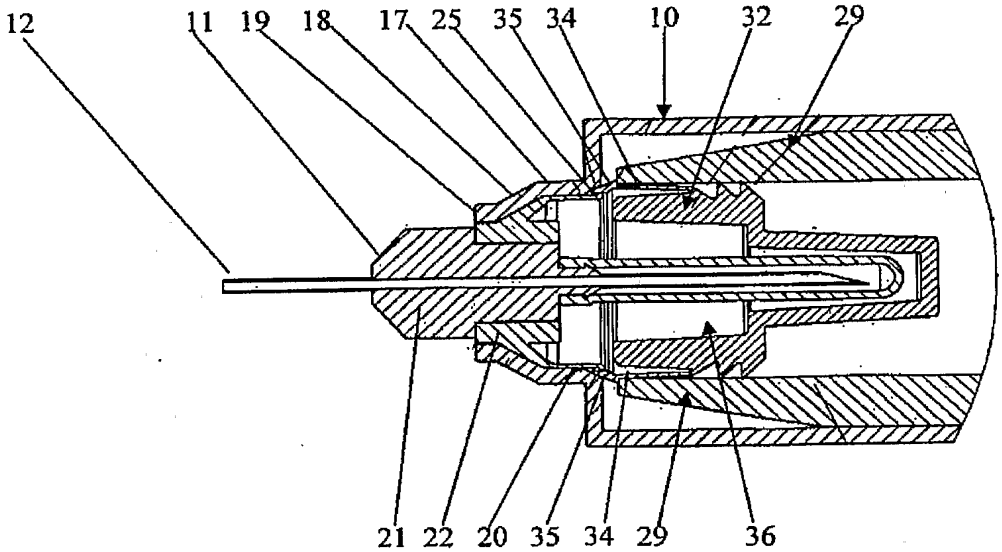

FIG 6

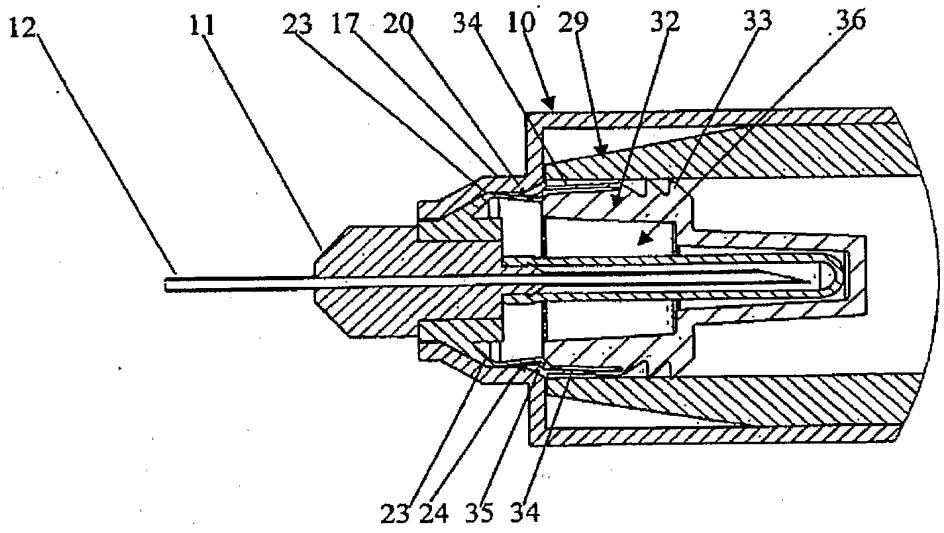

FIG 7

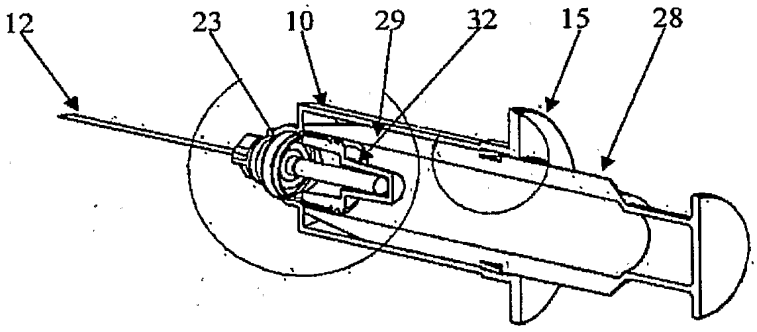

FIG 8

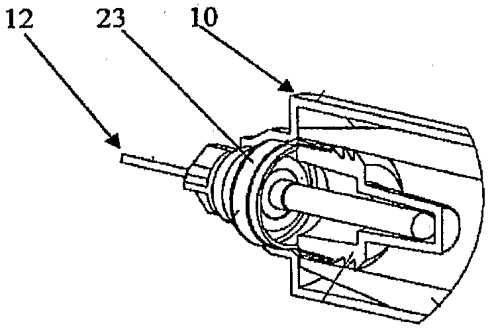

FIG 9

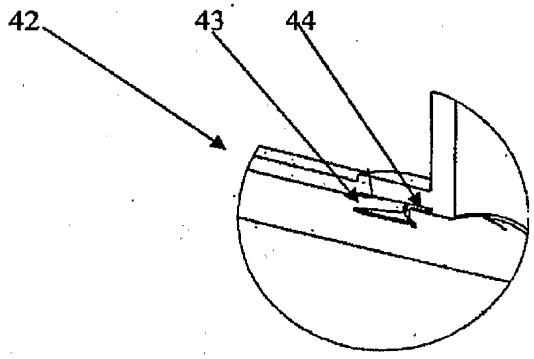

FIG 10